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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/577,266    05/23/00    JOHNSON    W    601-1-057N

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HM12/0925

EXAMINER

HARTTER, A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/25/01

4

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/577,266

Applicant(s)

JOHNSON ET AL.

Examiner

Amy Hartter

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 & 46-47 drawn to a method of generating a genetic reference data set, classified in class 702, subclass 19. There are two species elections, which are both, required to be elected from within this Group. If this Group is elected then an election of one of the following species in each specie election requirement is also required. They are:
  - A. Specific disease choice, e.g. as listed in claim 3.
  - B. Nucleic acid or protein choice
- II. Claims 5-14 & 44-45, drawn to a method of estimating genetic susceptibility to a developmental disability, classified in class 702, subclass 19. The same species elections requirements as applied to Group I apply to this Group that is, if this Group is elected then an election of one of the above species in each specie election requirement is also required.
- III. Claims 15-18, drawn to a method of estimating genetic susceptibility to a developmental disability, classified in class 702, subclass 19. The same species elections requirements as applied to Group I apply to this Group that is, if this Group is elected then an election of one of the above species in each specie election requirement is also required.

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- IV. Claims 19-29, drawn to a method of estimating genetic susceptibility in an offspring, classified in class 702, subclass 19. The same species elections requirements as in Group I apply to this Group, also. There is additionally a third species election within this Group, which is the election from either treatment or non-treatment species. If this Group is elected then an election of one of the above species in each specie election requirement is also required.
- V. Claims 30-32, drawn to an isolated nucleic acid classified in class 536, subclass 23.1.
- VI. Claims 33-38 & 40-43, drawn to a PCR primer or an isolated nucleic acid that can distinguish between specific sequences, classified in class 536, subclass 23.1.
- VII. Claim 39, drawn to an isolated nucleic acid for simple hybridization classified in class 536, subclass 23.1.

#### **DETAILED ACTION**

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-IV and V-VII are related as product and processes of use and products respectively. The inventions can be shown distinct if either of both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

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used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids in Groups V-VII can be used in distinct processes of the inventions of Groups I-IV. One use is directed to polypeptide expression, and yet another expression modulation. Nucleic acids of Groups I-IV can also be used in antisense therapy, which is also clearly a distinct usage of such nucleic acids. Thus these products are distinct from their associated processes.

Groups I-IV are distinct processes with different essential steps as noted in each of the brief invention Group descriptions given above. Similarly, each of Groups V-VII has distinct usage functions, which define these products separately. Thus, each of Groups I-VII are distinct due to requiring separate searches therefore documenting the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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**Conclusion**

Any inquiry concerning this communication or earlier communications from this examiner should be directed to Amy Hartter whose telephone number is (703) 305-1696. The examiner can normally be reached M-F from 8:00 to 4:30 p.m. (Eastern Time).

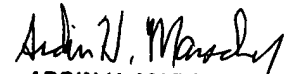
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 305-4028. The fax phone numbers for the group are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature relating to the status of this application should be directed to the Patent Analyst, Kim Davis, whose telephone number is (703) 305-3015 or to the Technical Center Receptionist whose telephone number is (703) 308-0196.



Amy Hartter

(703) 305-1696



ARDIN H. MARSCHEL  
PRIMARY EXAMINER